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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,063	12/11/2003	Christoph Widmer	32784US5	7834

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EXAMINER	
WARREN, DAVID S	

ART UNIT	PAPER NUMBER
2837	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/733,063	WIDMER, CHRISTOPH
	Examiner	Art Unit
	David S. Warren	2837

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/11/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See specification pages

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 4, 17 – 20, and 22 – 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Moro et al. (5,045,266). Regarding independent claims 1 and 20, Moro discloses the use of hearing device (col. 1, lines 62 – 64) and a substance provided on the surface of the hearing device (col. 3, lines 14 – 19). The Examiner maintains that *release* of a substance will place the substance at the surface of the hearing aid shell. Regarding claims 2 and 22, Moro discloses the hearing aid electronics fit within a cavity within the earmold, thus making the

earmold a "shell." Furthermore, for the substance to be released, it must be within the shell. (For the purposes of this rejection, shell and earmold are deemed synonymous). Regarding claims 3 and 23, Moro states that the substance is controllably released (col. 3, lines 16 – 19). Regarding claims 4, 17, 18 and 24, Moro discloses the use of germicides, fungicides, antibiotics, analgesics, etc. All are deemed functionally equivalent to being "antibiotically active" or "an antimicrobial agent." Regarding claim 19, migration of the medically active ingredients to the surface of the Moro hearing device shell, will provide the functional equivalent of a "film."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 5 – 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al. (discussed supra) and in view of Zaffaroni (3,996,934). The teachings of Moro have been discussed supra. Regarding claims 5, 11 and 12, Moro does not disclose the use of a rough surface. Zaffaroni discloses the use of a porous surface, wherein any porous surface will

have a degree of roughness (col. 4, lines 51 – 57). The Examiner notes that the porous structure of Moro applies to both a covering membrane and the matrix (which is impregnated with the medically active ingredient). Regarding claims 6, 8, and 10, both Moro and Zaffaroni disclose placing material within the matrix (or shell) – as defined by Applicant, this will constitute a film. Regarding claim 7, the Examiner maintains that all substances have structure, e.g., molecular structure, polymeric structure, etc. Regarding claim 9, Zaffaroni discloses matrix dimensions of 50 angstroms (or less) to 100 microns, a matrix of 50 angstroms will deliver a substance of 50 angstroms or less, certainly 50 angstroms can be fairly interpreted as a "micro-structure." Regarding claim 13, ("slow" is a relative term) both Moro and Zaffaroni disclose slow release (e.g., see Zaffaroni, col. 12, last sentence). Regarding claims 14 – 16, Zaffaroni does not specifically disclose the use of a liquid, gel, and/or paste, but instead states "the viscosity" (col. 4, lines 57 – 64) may be chosen in accordance with the matrix pore size. The Examiner maintains that this is functionally equivalent to using structures, micro-structures, with a liquid, gel, and/or paste. In other words, the viscosity (i.e., liquid, gel, or paste) may be varied in accordance with pore size to achieve a desired active ingredient release rate – which is vital in administering medicaments. The limitations of claim 21 are discussed supra with regard to claims 5 – 9. It would have been obvious to one of ordinary skill in the art to combine the teachings of Moro and Zaffaroni to obtain a hearing device with a substance applied thereto, wherein the shell provides a matrix for the substance.

The motivation for making this combination is improved transdermal drug delivery.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent ot Leonard et al. ('525) discloses the use of Applicant's substance and matrix.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Warren whose telephone number is 571-272-2076. The examiner can normally be reached on M-F, 9:30 A.M. to 6:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Martin can be reached on 571-272-2800 ext 37. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

MARLON T FLETCHER
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).